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10/518,001

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Monier Tadros

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|---------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/518,001 | Applicant(s) TADROS, MONIER | |
| | Examiner Maryam Monshipouri | Art Unit 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-28 and 44-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5-28 and 44-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/07, 12/04, 3/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's response to restriction requirement filed 12/27/07 and applicant's supplemental amendment of 2/6/08 are acknowledged. Applicant elected Group I (claims 1-28) without traverse. Claims 1, 4, 29-43 and 45-46 are canceled.

Claims 2-3, 528, 44, 47-54 drawn to DNA encoding biologically active protamine, single cell host cells and seeds comprising them and methods of recombinantly expressing them are under examination on the merits. All whole organism beyond a single cell comprising said DNA, including transgenic animals and plants are hereby withdrawn as drawn to non-elected invention.

On 2/18/2008 the examiner called applicant to negotiate allowance but said negotiations were not successful.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3, 5-28, 44, 47-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "functional fragment" and "biologically active" in claims 2 (and its dependent claims 5,10 and 44), claim 3 (and its dependent claims 6-9, 11-23, 45-54), claim 24 (and its dependent claim 25), claim 26 (and its dependent claims 27-28) are unclear. In page 9 of the disclosure applicant defined the phrase "biological active" protamine as a fragment displaying at least one of biological activities of protamine already know in the art. Said phrase remains indefinite because it is unknown which biological activity applicant is referring to. Similarly, the

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phrase “functional fragment” is indefinite. Because in page 10 of the disclosure applicant has defined this phrase as any protamine peptide or amino acid sequence retaining at least one of the biological activities as discussed in the prior art, retaining at least one common structural or antigenic determinant. It is unclear which “biological activities” applicant is referring to and what exact structural or antigenic determinants are intended. Hence, the metes and bounds of said phrases are unknown.

Claims 12-23, 29-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 12 the term “whole organism” in the preamble is directed to products such as bacteria, fungi, yeast, animal and plant cells as well as “whole organisms”. It is unclear what is the difference between “whole organism” in the preamble versus that used in the body of the claim. Appropriate clarification is required. Claims 13-23, 29-54 are merely rejected for depending from claim 12.

Claims 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13-19 appears to be a Markush claim within the Markush and is confusing. It is unclear, for example, whether the bacteria listed in each claim are “whole organism” or “host cell”.

Claims 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 appears to be a Markush claim within the Markush

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and is confusing. It is unclear, for example, how a eukaryotic host cell can be "tissue". Also it is unknown algae be a plant cell, seed or whole organism simultaneously. Also in line 2, the term "and" does not make sense. Appropriate clarification is required.

Claims 47-54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the bacteria recited in the Markush are "host cell" or "whole organism".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3, 5-28, 44, 47-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule comprising a nucleotide sequence encoding SEQ ID NO:32 inherently having antimicrobial activity, single cell host cells comprising said product and methods of expressing said product, does not reasonably provide enablement for "functional fragments" of SEQ ID NO:32, single cell host cells comprising said fragments and methods of use of said fragments wherein said fragments have no function.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

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The disclosure fails to teach which residues within claimed fragments must be retained such that said fragments retain the “biological activity” of SEQ ID NO:32, see 112 second rejection above. No examples of such residues are provided either. Current state of the art indicates that once more than 2-3 amino acids of a full-length polypeptide is simultaneously deleted the resultant “polypeptide fragments” does not necessarily retain the function of said full-length polypeptide. Therefore due to lack of sufficient guidance and examples provided and due to unpredictability of prior art as to which “functional fragments” retain the “biological activity” of SEQ ID NO:32 one of skill in the art has to go through the burden of undue experimentation in order to screen for those fragments that are supported by the disclosure and as such the claims go beyond the scope of the disclosure.

Since the DNA of claims 2-9, are not enabled, single cell host cells comprising said products (claims 11-23, 25, 44, 47-54) and methods of utilizing said products (claims 24-28) are not enabled either.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-3, 5-9, 10-12, 22, 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by McMahon et al. (Nature4, 364, 346-349, 1993). McMahon teaches (see figure 1) an isolated DNA sequence having 51% identity to SEQ ID NO:32 of this

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invention (see attached sequence alignment). It's sequence can be considered to be a "functional fragment" (see 112 second reaction above) of SEQ ID NO:2 of this invention, anticipating claim 2. In page 348, Mc Mahon teaches vectors and expression cassettes utilized for its DNA expression, anticipating claims 3, 5-10). McMahon specifically teaches CV-1 and CHO cells transfected with its DNA sequence, anticipating claims 11-12, 22 as well as methods of transecting said host cells before recombinantly expressing said DNA sequence, anticipating claims 3, 5-10, 24-26 of this invention.

No claim is allowed.

Note: SEQ ID NO:32 is free of prior art. Further , the prior art fails to suggest such specifically claimed DNA sequence. Hence said sequence is also non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

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